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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,852	12/10/2003	Frederick L. Hall	14230-010002	4628

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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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08/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/733,852

Applicant(s)

HALL ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-69, 72-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66 and 72-80 is/are rejected.
- 7) ☒ Claim(s) 67-69 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Status of Application, Amendments and/or Claims

The amendment filed 08 June 2007 has been entered in full. Claims 66-6972-80 are pending and under examination.

Withdrawn Objections And/Or Rejections

The rejection to claims 66-69 and 72-80 under 35 U.S.C. 112, first paragraph, scope of enablement, as set forth at pages 2-6 of the previous Office Action (08 May 2007), is *withdrawn* in view of the amendment (08 June 2007).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 66, 72-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Oppermann et al., Publication No. US 2005/0250936 A1. Oppermann et al. claims and is entitled to priority of 09/375,333, filed 8/16/99, for the disclosure relied upon.

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Oppermann et al. is not entitled to priority of provisional application no. 60/103,418 filed 10/7/98, for this disclosure. The instant application claims and is entitled to priority of 09/624,874, filed 7/21/00, for the present claims. The instant application is not entitled to priority back of provisional application no. 60/145,488 filed on 7/21/99, for the present claims.

Oppermann et al. teach that the TGF beta superfamily includes inhibin (para. 0003 and 0027). The polypeptides of the inhibin group appear to play a role in the regulation of cell growth (para. 0006, 0157 and 0223). Oppermann et al. teach inhibin alpha and beta (para. 0057). Oppermann et al. teach fusion proteins comprising TGF beta superfamily members and a collagen binding domain and nucleic acids encoding the fusion proteins (para. 0043, 0051, 0052, 0081, 0193, 0170, 0176, 0179, 0180, 0186, 0190 and claims). Oppermann et al. teach vectors, promoters, host cells such as prokaryotic and eukaryotic cells and methods of making recombinant proteins (para. 0010, 0016, 0017, 0040, 0080, 0128, 0133, 0138). Oppermann et al. teach pharmaceutical compositions comprising the fusion proteins (para. 0079 and 0164).

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 76, 78-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 76, 78 and 79 are indefinite because it is not clear if the instant claims are drawn to a transgenic animal or cells in culture. Amending claim 76 to recite, "an **isolated** host cell.." and claims 78 and 79 to recite, "..wherein the host **cell** is.." would be remedial.

Claim 80 is indefinite because it is drawn to a pharmaceutical composition comprising a fusion protein in a pharmaceutically acceptable carrier with no intended use. The metes and bounds of the instant claim cannot be determined because when the term "pharmaceutical" is used in the preamble of a claim, its intended use as a pharmaceutical must be shown.

Claim Rejections-35 USC § 112, First Paragraph, Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 80 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claim is drawn to a pharmaceutical composition comprising a fusion protein in a pharmaceutical acceptable carrier. When the term "pharmaceutical" is used in the preamble of a claim, its intended use as a pharmaceutical must be shown. The intended use of the claim as a pharmaceutical is imputed to mean intended *in vivo*

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therapeutic use. The instant claims fail to teach an intended use for the claimed pharmaceutical composition and thus reads on treating any type of disease and/or condition, such as heart disease, obesity, HIV, cancer, diabetes, etc. The specification fails to provide any guidance on the *in vivo* use of the claimed composition to treat any disease and/or condition. No examples of treatment are provided to treat any disease and/or condition. Furthermore, it could not be predicted that the data disclosed in the specification would be in any way correlative with therapeutic agents for treatment of any type of disease and/or condition.

Due to the large quantity of experimentation necessary to show a correlation between the claimed pharmaceutical composition and treatment of any disease and/or condition, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to same, the complex nature of the invention and the breadth of the claims which fail to recite limitations regarding intended use, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Claim Objections

Claims 67-69 are objected to because they depend from a rejected claim.

Conclusion

Claims 66, 72-80 are rejected.

Claims 67-69 are objected to.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RMD
8/23/07

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER

AU 1647 8/24/07